REMARKS/ARGUMENTS

This is in response to the final Office Action dated April 3, 2003. A three-month extension request and notice of appeal was filed on October 1, 2003. The Appeal Brief was due on December 1, 2003. Applicants are submitting a Request for Continued Examination (RCE) under 37 CFR § 114 with this preliminary amendment along with a five (5) month extension of time, extending the period for response from the date of the final rejection to May 1, 2004. Accordingly, this response is timely filed.

In view of the following remarks and amendments, Applicants respectfully submit that all pending claims are now in condition for allowance.

Claims 1 and 3 and 16 are currently pending in the present application. Claims 2 and 8-15 have been withdrawn from consideration and claims 4-7 have been cancelled. The Office Action withdrew Claims 17-24 from consideration, under a Restriction Requirement, as being directed to a non-elected invention than was originally presented, which Applicants are traversing. Applicants have also added new claims 25 - 28. Claim 1 is an independent claim. Claim 3 has also been amended to be an independent claim.

The Office Action maintains the objection due to a missing space at page 19, line 21. Claims 1 and 16 are rejected under 35 USC § 102 (e) and Claims 1 and 3 are rejected under 35 USC § 102(b).

1. Restriction/Election

The Office Action has withdrawn Claims 17-24 from consideration, under a Restriction Requirement, as being directed to a non-elected invention than was originally presented. Such a Restriction Requirement is proper when:

(A) The inventions are independent or distinct as claimed: and

(B) There is a serious burden on the examiner, unless restriction is required.

A serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification or separate status in the art or a different field of search as defined in MPEP § 808.02.

Applicants contend that the Restriction Requirement is improper because the Office Action has failed to demonstrate a serious burden on the Examiner necessitating a Restriction Requirement. Moreover, claims 1-6 are drawn to compositions containing the polynucleotide sequence of SEQ ID NO:1 contained in the various expression systems of Claims 5 and 6, including plasmid, viral and E.coli expression vectors. Claims 1-6 were examined in the first Office Action. Thus, no showing has been made that it would be a serious burden to search and examine Claims 17-24, drawn to the same polynucleotide sequence of SEQ ID NO:1 and fragments comprising nucleotides 1-999 of SEQ ID NO:1 also contained in suitable expression systems, such as the E. coli expression system of claim 19, in the same application.

Moreover, Applicants contend that new claims 17-28 are arguably in the same field of search, patent classification and subclassification as the elected Group I claims of the original restriction requirement of March 1, 2001, paper no. 5, and should all be examined together. The Group I claims, claims 1 and 4-7 and 16, which are under examination in this application, are classified under Classification 514 (Drug, Bio-Affecting and Body Treating Compositions) and Subclassification 44 (Polynucleotide-DNA). Applicants contend that claims 17-28 are in the same field of search, the same class/subclass, and have the same status in the art. Secondly, the

Restriction Requirement fails to establish a burden on the Examiner and thus the aforementioned claims should all be examined together in the instant application.

Applicants have already paid any applicable additional claims fees for adding new claims 17-24 in the previous office action. If the Restriction Requirement is maintained, Applicants will be burdened with having to file one or more divisional applications, with the attendant application filing fees, to recapture unnecessarily restricted subject matter for which Applicants have already paid claim fees.

Applicants respectfully request claims previously presented but unentered claims 17-24 be rejoined with pending claims 1,3, and 16 and new claims 25-28 added for examination in the instant application.

2. Objections

The Office Action objects to the disclosure because of a missing space at page 19, line 21. The January 21, 2003 reply to the July, 26, 2002 Office Action attempted to correct the error. However, the correction did not correspond to that which was originally presented at that location and was therefore not entered. The amendment presented herewith corrects this error. Applicants respectfully request the objection be reconsidered and withdrawn.

3. Rejection under 35 USC §102(e) as anticipated by Meinersmann, *et al*

Claims 1 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Meinersmann *et al* (US Pat. 5,837,825) effective filing date, November 17, 1998. Meinersmann teaches a truncated flaA fused to LT (B-subunit). In Meinersmann, the

inventors disclosed an attempt to produce a fusi n construct encoding the entire flaA gene but admitted a lack of success but was able to obtain a truncated version of the gene. (column 8, lines 62). The Office Action states that the claimed invention of Claim 1 is directed to any polynucleotide that encodes an immunogenic polypeptide and need not comprise nucleotides 13-1015 of SEQ ID No. 1. The Office Action further states that Claim 1 recite open language and does not exclude flaA polynculeotides that are in addition to the recited range of nucleotides. The Office Action also rejects Claim 16 which depends from Claim 1.

Response

By this Amendment, Claims 1 and 16 are amended, thus overcoming the rejections. Newly amended independent claim 1 is drawn to an "isolated and purified" polynucleotide sequence encoding an immunogenic polypeptide that is a portion of the flaA coding region of Campylobacter, the polynucleotide sequence consisting essentially of nucleotides 1-999 of SEQ ID NO:1. Claim 16 is dependent upon claim 1 and adds the additional limitation that the claimed polynucleotide sequence is expressed in an expression system such as plasmid, viral and E.coli expression vectors.

Anticipation of a claim by a prior art reference can only exists if each and every element is described in a single prior art reference. If a claim is narrowly limited, anticipation is avoided if the claimed sequences differs from that found in the prior art. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); *Ex parte Goeddel*, 5 USPQ2d 1449, 1451 (Bd. Pat. App. & Interf. 1987).

Amended Claim 1 has been amended to recite the transitional phrase "consisting essentially of" nucleotides 1 – 999 of SEQ ID NO.:1 which encodes the highly immunogenic portion of the flaA gene encompassed within this region vice nucleotides 13-1015 as originally filed. Regions outside of this sequence limit are not claimed. Applicants are making this amendment to clarify the subject matter they are seeking to patent. The amended claim 1 is fully supported by SEQ ID NO.:1 of the Sequence Listing as originally filed which only contains 999 nucleotides. Thus, there is no new matter.

Meinersman, *et al* fails to teach the precise, partially closed sequences of the instant invention as recited in amended claim 1 and, therefore, does not anticipate each element of the claim. Thus, there are no grounds for a *prima facie* case of anticipation under 35 U.S.C. (102e) regarding independent Claim 1. Since Claim 16 is dependent upon Claim 1, Meinersman, *et al* also fails to anticipate Claim 16.

Applicants respectfully request the rejection under 35 U.S.C. §102(e) be reconsidered and withdrawn.

4. Rejections under 35 USC §102(e) as anticipated by Schultz, *et al*

Claim 1 is rejected under 35 U.S.C.§102(e) for being anticipated by Schultz, *et al* (US Pat. 6,270,974), effective filing date of March 13, 1998. The Office Action states that the instantly claimed invention of Claim 1 is directed to any polynucleotides 13-1015 of SEQ ID No. 1 that encodes an immunogenic polypeptide and need not comprise nucleotides 13-1015 of SEQ ID No. 1, but must be a polynucleotide sequence taken from the recited region set forth by nucleotides 13-1015 of SEQ ID No. 1 and must encode at

least 10 amino acids (i.e. a size capable of be recognized as foreign). The Office Action states that the Applicant's arguments are not commensurate in scope with the claimed invention. The Office Action also states that Shultz, et al anticipates the claimed invention since Shultz, *et al* shares 100% homology with 30 nucleotides of SEQ ID NO. 1. and encodes amino acids 97-106 of SEQ ID No. 2.

Response

Anticipation of a claim by a prior art reference can only exists if each and every element is described in the reference. If a claim is narrowly limited, anticipation is avoided if the claimed sequences differs from that found in the prior art. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); *Ex parte Goeddel*, 5 USPQ2d 1449, 1451 (Bd. Pat. App. & Interf. 1987).

Amended Claim 1 has been amended to recite the transitional phrase "consisting essentially of" nucleotides 1 – 999 of SEQ ID NO.:1 which encodes the highly immunogenic portion of the flaA gene encompassed within this region vice nucleotides 13-1015 as originally filed. Regions outside of this sequence limit are not claimed, as stated above. The polynucleotide sequence of SEQ ID No. 1 encodes an immungenic polypeptide of flaA disclosed in SEQ ID No. 2.

Schultz, *et al* discloses a polynucleotide sequence encoding a portion of flaA gene of *Campylobacter*, wherein the polynucleotide sequence is contained in a portion of the DNA sequence of SEQ ID NO. 1. Claim 1 has been amended to include partially closed language in order to limit the claimed sequence to nucleotides 1- 999 of SEQ ID NO. 1. As amended, Claim 1 recites a specific nucleotide sequence which is not taught by Schultz, *et al.* that is capable of encoding a peptide with specific immunological

characteristics. Thus, Schultz et al does not anticipate each and every element of independent claim 1 and, as such, is not anticipatory prior art under 35 U.S.C. §102(e). Therefore, it is requested that the rejection be reconsidered and withdrawn.

5. Rejections under 35 USC § 102(b) as anticipated by Alm, *et al*

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Alm *et al* (May 1993). Alm, *et al* discloses a polynucleotide sequence encoding a portion of the flaA gene of *Campylobacter*, wherein the polynucleotide sequence is a portion of the DNA coding sequence for flaA obtained from *C.coli* VC167-T2, that was also used by Applicant. The Office Action states that Claim 1 is not limited to the polynucleotides of SEQ ID No. 1, but is directed to a polynucleotide that encodes an immunogenic polypeptide and the immunogenic polypeptide is not required to evidence the functional characteristic of being useful in reducing colonization of *Campylobacter*. The Office Action further states that that the claimed invention of Claim 1 is directed to any polynucleotide that encodes an immunogenic polypeptide and need not comprise SEQ ID No. 1, but must be a polynucleotide sequence taken from SEQ ID No. 1 and encode at least 9 – 10 amino acids.

Response

Anticipation of a claim by a prior art reference can only exists if each and every element is described in a single prior art reference. If a claim is narrowly limited, anticipation is avoided if the claimed sequences differs from that found in the prior art. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); *Ex parte Goeddel*, 5 USPQ2d 1449, 1451 (Bd. Pat. App. & Interf. 1987).

Claim 1 has been amended to include partially closed language in order to specify the claimed sequences of nucleotides 1- 999 of SEQ ID NO. 1. As amended, Claim 1 recites a specific nucleotide sequence capable of encoding a peptide with specific immunological characteristics. Alm, *et al* discloses conserved and hypervariable regions of flaA among strains of *Campylobacter* based on polymerase chain reaction (PCR) amplification. Alm, *et al*, however, as a single reference, does not teach the precise regions recited in Claim 1, as amended. Since each element is not taught or anticipated by Alm, *et al*, Applicants respectfully request that the rejection of Claims 1 be reconsidered and withdrawn. Claim 3 has also been amended to include partially closed language. As such, Alm, *et al* fails to teach the specific polypeptide sequence of Claim 3. Applicants respectfully request that the rejection of Claims 3 be reconsidered and withdrawn.

6. Rejections under 35 USC § 102(b) as anticipated by Rasmussen *et al*

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Rasmussen *et al* (1996). Rasmussen, *et al* discloses a polymerase chain reaction (PCR) diagnostic assay based on the VC167 sequence using PCR primers selected from conserved regions. Expected products from the PCR assay are 810 bp and 813 bp. The Office Action states that the amplified products of the primers anticipates the instant invention, as claimed, since the sequence was publically available as disclosed by Logan *et al* (1989)(reference cited in Applicants specification and incorporated by reference by Rasmussen, *et al*).

Resp nse

Anticipation of a claim by a prior art reference can only exists if each and every element is described in a single prior art. If a claim is limited, anticipation is avoided if the claimed sequences differs from that found in the prior art. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); *Ex parte Goeddel*, 5 USPQ2d 1449, 1451 (Bd. Pat. App. & Interf. 1987).

Claim 1 has been amended to include partially closed language in order to limit the claimed sequences to nucleotides 1- 999 of SEQ ID NO. 1. Claim 1 as amended, is narrowly limited to include a precise sequence selected on its ability to encode an amino acid sequence capable of conferring immunogenicity to *Campylobacter*. Rasmussen, *et al* fails to teach the precise sequence of amended Claim 1, encoding the desired immunologic characteristics. Therefore, Applicants request that the rejection based on Rasmussen be reconsidered and withdrawn.

7. Rejections under 35 USC § 112, 1st Paragraph

In new grounds for rejection, claims 1, 3 and 16 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 was previously amended to recite nucleotides 13-1015. However, the DNA sequence of SEQ ID NO:1 has only 999 nucleotides. Therefore, claim 1 recites new matter. Claim 16 is rejected since it depends from claim 1.

Similarly, Claim 3, is rejected because it recites a DNA sequence encoding an immunogenic polypeptide comprising amino acids 5-338 of SEQ ID NO. 2 where SEQ ID NO. 2 had only 330 amino acids and that the additional nucleotides were not disclosed in SEQ ID NO 2. Therefore, claim 3 recites new matter.

Response

By this Amendment, Claim 1 is amended, overcoming the rejection. Claim 1, as presented in the provisional application, filed December 22, 1998, as well in the original non-provisional application, claimed the entire region described in SEQ ID No. 1. Furthermore, the method of construction of this sequence is described in the specification such that the construct would include regions I, II, and III of the flaA gene. The sequence contained in SEQ ID No. 1 corresponds to the region contained in nucleotides 13 – 1015 of the VC 167 described on page 1856 in Guerry, *et al*, J. Bacteriology, vol, 172 (4), p 1853 - 1860 (1990) and in the specification.

Furthermore, based on the PCR sequences used and method of construction of the flaA insert described in the specification, one skilled in the art would be able to construct the sequence in SEQ ID No. 1. Therefore, it is clear from the written description that the applicants had possession of the invention. However, the Claims were erroneous due to typographical errors. Since the original provisional application from which the non-provisional depends disclosed and claimed the entire sequence in SEQ ID No. 1, there is no new matter presented. However, Claim 1 has been amended to accurately reflect the sequence claimed in the provisional and original non-provisional applications and to include partially closed language. Therefore, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Since Claim 1 should now be allowed, it is respectfully requested that the rejection of Claim 16, which is dependent on Claim 1, also be reconsidered and withdrawn.

Claim 3, is rejected because it was previously amended to recite a DNA sequence encoding an immunogenic polypeptide comprising amino acids 5-338 of SEQ ID NO. 2 where SEQ ID NO. 2 had only 330 amino acids and that the additional nucleotides were not disclosed in SEQ ID NO 2. Applicants contend that SEQ ID NO. 2, as originally disclosed and claimed, has 333 amino acids. Claim 3 is amended to reflect that only amino acids 1 – 333 of SEQ ID NO 2 is being claimed. The Applicants, therefore, request reconsideration of the rejection and the rejection withdrawn.

8. Rejection under 35 USC § 112, 2nd Paragraph

Claim 16 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claiming the subject matter Applicant regards as the invention. The Office Action states that the polynucleotide in Claim 1 is "isolated and purified" but is not associated with any expression system. The Office Action also states that Claim 1 does not indicate any way the polynucleotide is capable of being expressed, based on nucleotide sequence alone. The Office Action further questions the definition of "suitable" expression systems, since no point of reference is provided. The Office Action points out that original Claim 5 defined specific expression systems that were suitable. The Office Action further requests clarification of the polynucleotide sequence claimed.

Response

By this amendment, Claim 1 and 16 are amended, overcoming the rejection. Claim 1, from which Claim 16 depends, is amended to include partially closed language. As amended, Claim 1 and Claim 16, claim a specific polynucleotide sequence. Additionally, the use of the word "suitable" has been deleted and replaced with examples of expressions systems expressed as a Markush group.

Claim 16 should now be consistent with the requirements of 35 U.S.C. §112, second paragraph. Applicants request that the rejection under 35 U.S.C. §112 be reconsidered and withdrawn.

9. Rejection under 35 USC § 102(b) as anticipated by Logan, *et al*

Claims 1, 3, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Logan et al (1989). Logan allegedly discloses an isolated and purified DNA molecule encoding the *Campylobacter* FlaA gene including the nucleotide sequence disclosed in SEQ ID NO. 1 and the polypeptide sequence of SEQ ID NO 2. The Office Action concludes that the reference anticipates the claimed invention.

Response

A prior art will anticipate only if it describes every element of the claim in a single prior art reference. If a claim is narrowly limited, anticipation is avoided if the claimed sequences differs from that found in the prior art. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); *Ex parte Goeddel*, 5 USPQ2d 1449, 1451 (Bd. Pat. App. & Interf. 1987). Additionally, the prior art must have a disclosure adequate to enable the public to make and use the invention and to place the

public in possession of the invention. *Scripps Clinic*, 927 F.2d at 1580; *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

Logan, *et al* presents a nucleotide and amino acid sequence of *C. coli* VC 167 flagellin. (Logan, *et al*, page 3034). Claims 1 and 3 are amended to more specifically claim a specified sequence which is a defined portion of the flaA gene with encoded peptide sequence possessing specific, intended immunological properties. Logan, *et al*, fails to teach or enable one skilled in the art and without further experimentation, how to make and use the claimed invention in the instant application, i.e. to construct a peptide with the characteristics described in the instant application. Although the sequence of VC 167 is listed in Logan, data is not presented that would enable one skilled in the art to select appropriate regions capable of conferring desired and intended immunological properties of instant application. Additionally, nothing in the reference implicates or suggests the use of specific flagellin sequences to confer immunity without inducing Guillain-Barre Syndrome (GBS) which is an object of the current application. Therefore, the reference does not teach each element of the claims as recited in the current application. Consequently, Logan, *et al* does not anticipate the instant claims Claims 1, 3, and 16, as amended. Applicant, therefore, respectfully request that the rejection be reconsidered and withdrawn.

Applicants respectfully submit that all claims are in condition for allowance and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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Date: April 27, 2004